

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Viggnia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/670,739	09/27/2000	Brian G. Scrivens	P-5015 7708		
759	90 07/31/2003				
Richard J Rodrick Esq Becton Dickinson and Company 1 Becton Drive			EXAMINER  COLE, MONIQUE T		
			1743	. 5	
•			DATE MAILED: 07/31/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

					# >
		Applicati	on No.	Applicant(s)	42-6-
		09/670,7	39	SCRIVENS ET AL.	
Office Action Summary		Examine	r	Art Unit	
		Monique	T. Cole	1743	
Period fo	The MAILING DATE of this communic r Reply	cation appears on th	e cover sheet with	the correspondence address	
THE I - Externanter - If the - If NO - Failu - Any r	ORTENED STATUTORY PERIOD FO MAILING DATE OF THIS COMMUNIC missions of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this commu period for reply specified above is less than thirty (30) period for reply is specified above, the maximum stature to reply within the set or extended period for reply weply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b).	CATION.  f 37 CFR 1.136(a). In no evinication.  I days, a reply within the starutory period will apply and will, by statute, cause the apply.	vent, however, may a rep tutory minimum of thirty ( vill expire SIX (6) MONTH olication to become ABA	y be timely filed  30) days will be considered timely.  IS from the mailing date of this communication.  IDONED (35 U.S.C. § 133).	
1) <b></b>	Responsive to communication(s) file	d on 08 May 2003			
2a)□	·	b)⊠ This action is			
_ <u></u>	Since this application is in condition	,—		ers prospecution as to the marite is	
3) Dispositi	closed in accordance with the practic on of Claims				
4)🖂	Claim(s) 1-18 is/are pending in the a	pplication.			
	4a) Of the above claim(s) is/are	e withdrawn from co	nsideration.		
5)[	Claim(s) is/are allowed.				
6)🖂	Claim(s) 1-8,13 and 14 is/are rejected	d.			
7)🖂	Claim(s) 9-12 and 15-18 is/are object	ed to.			
8)□	Claim(s) are subject to restricti	ion and/or election r	equirement.		
Applicati	on Papers				
9)□ :	The specification is objected to by the	Examiner.			
10) 🗌 -	The drawing(s) filed on is/are: a	a)□ accepted or b)□	objected to by the	Examiner.	
	Applicant may not request that any object	ction to the drawing(s	) be held in abeyan	ce. See 37 CFR 1.85(a).	
11) 🔲 -	The proposed drawing correction filed	on is: a)□ a	pproved b)☐ dis	approved by the Examiner.	
	If approved, corrected drawings are requ	uired in reply to this O	ffice action.		
12) 🗌 -	Γhe oath or declaration is objected to t	by the Examiner.			
Priority u	nder 35 U.S.C. §§ 119 and 120				
13)	Acknowledgment is made of a claim f	or foreign priority ur	nder 35 U.S.C. §	119(a)-(d) or (f).	
a)[	☐ All b)☐ Some * c)☐ None of:				
	1. Certified copies of the priority d	ocuments have bee	en received.		
	2. Certified copies of the priority d	ocuments have bee	en received in App	olication No	
* S	3. Copies of the certified copies of application from the Internatee the attached detailed Office action	itional Bureau (PCT	Rule 17.2(a)).	_	
14) <u></u> □ A	cknowledgment is made of a claim for	r domestic priority u	nder 35 U.S.C. §	119(e) (to a provisional application	1).
	)  The translation of the foreign lang  Acknowledgment is made of a claim fo		•		
Attachmen	t(s)	-	_		
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PT nation Disclosure Statement(s) (PTO-1449) Pap	•		mmary (PTO-413) Paper No(s)ormal Patent Application (PTO-152)	
J.S. Patent and To PTO-326 (Re		Office Action Summa	гу	Part of Paper No. 5	

Application/Control Number: 09/670,739

Art Unit: 1743

#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 103

- 1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 2. Claims 1-8, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,454,945 to Weigl et al. (herein referred to as "Weigl").

Weight eaches a microfluidic system comprising a plurality of inlets; means for controlling fluid flow through at least one of said inlets connected with said inlet; a laminar flow channel in fluid communication with said inlets; at least three outlets in fluid communication with said laminar flow channel; and means for controlling fluid flow through at least one of said outlets connected with said outlet (col. 7, lines 15-23). Detection and analysis is done by optical means (col. 8, lines 34-35). The apparatus may include a transparent cover plate (col. 16, lines 5-6). The input or sample stream may be any stream containing particles of the same or different size, for example blood (col. 9, lines 7-8). In a preferred embodiment, when the sample stream is whole blood, small ions diffuse rapidly across the channel, whereas larger particles diffuse slowly (col. 9, lines 16-24). The inlets need only be sized large enough to conduct the streams of parallel laminar flow (col. 10, lines 50-52). The width and depth of the inlet and outlet channels must be large enough to allow the passage of the undesired particles (col. 10, lines 63-64). In Figure 4, there is exemplified a microchannel configuration having multiple product channels to separate different sized particles.

Weigl differs from the instantly claimed invention in that it separates smaller particles from the sample stream instead of larger particles. However, Weigel teaches that the channels included therein may be modified according to the preference of the person using the device.

"The inlets and outlets may be as long, deep and wide as required for the system of which they are a part." (col. 10, lines 57-59). Thus, given this disclosure, it would have been obvious to one having ordinary skill in the art to modify the channels taught in Weigl to isolate larger particles in lieu of smaller particles if the desired end result was to capture larger particles.

# Response to Arguments

- 3. Applicant's arguments, see Paper No. 4, filed 5/8/2003, with respect to the Parce reference have been fully considered and are persuasive. The prior rejection of claims 1 and 3-5 has been withdrawn.
- 4. Applicant's arguments, see Paper No. 4, filed 5/8/2003, with respect to the Columbus reference have been fully considered and are persuasive. The prior rejection of the claims has been withdrawn.
- 5. Applicant's arguments, see Paper No. 4, filed 5/8/2003, with respect to the rejection(s) of claim(s) 1, 2, 4-8, 13 and 14 under 35 USC 102(e) as anticipated by Weigel have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Weigl.

Applicant has asserted that in contrast to the present invention, Weigl does not disclose the use of "hardware" to achieve the separation of particles of different size and that the product of interest in of a different size. However, the Examiner would have to disagree with Applicant's

Application/Control Number: 09/670,739

Art Unit: 1743

assertion regarding the lack of hardware. Clearly, Weigl teaches channels which inherently contain walls to direct the flow therein. This is certainly equivalent to the separation channels Applicant discusses on page 4, last two lines through the top of page 5. Moreover, Weigl explicitly teaches in the brief description of Figure 4 that the microchannel configuration has multiple product channels to separate different sized particles.

The Examiner agrees with Applicant's assertion that Weigl does not teach isolating larger particles within the apparatus, but as mentioned in the rejection above, it would have been obvious in light of Weigl's disclosure to modify the channel size to obtain the desired particle size.

## Allowable Subject Matter

- 6. Claims 9-12 & 15-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 7. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest a method for obtaining a liquid sample having an increased cellular or particulate concentration for optical examination wherein notches are utilized to separate larger desired particles from smaller particles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 703-305-0447. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the

Art Unit: 1743

organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0661.

M. Ch Monique T. Cole

Examiner

Art Unit 1743

MC **MC** July 15, 2003